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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,807	04/17/2002	Toshiaki Kumazawa	2994.1	2129
5514	7590	11/23/2005	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			CEPERLEY, MARY	
		ART UNIT	PAPER NUMBER	
		1641		

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/018,807	KUMAZAWA ET AL.
	Examiner Mary (Molly) E. Ceperley	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 and 15-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/25/04; 1/11/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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1) Applicants are again requested to provide translations of the documents cited in paragraph 1) of the March 14, 2005 Office action. Any submission related to this request must meet the requirements of 37 CFR 1.97.

2) Applicant's election without traverse of Group I, claims 1-13 and 15-17, in the reply filed on April 08, 2005 is acknowledged. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 1, it is unclear what is meant to be encompassed by the term "substituted or non-substituted organic group". This term includes structures such as biomacromolecules and

porphyrins and reactive functional groups such as hydrazines and peroxides none of which would appear to be operable for the intended purpose of the invention.

b) For claim 2, the term "silanol" (SiOH) does not correspond to any definition of "X" or "Y" of claim 1, i.e. it is not a "substituted or non-substituted organic group". Additionally, it is not clear how the "Si" of the " SiR^3R^4 " moiety would be attached to the SiOH (silanol) group.

c) In claim 4, it is unclear what is meant by the term "dimethylpolysiloxane". Is this a compound of formula [I] wherein "X" and "Y" are both "methyl"? Or are the groups "R¹" and "R²" both "methyl"?

d) In claim 5, it is unclear what moieties are meant to be included by the term "hydrophobic organic group". What feature makes an organic group "hydrophobic"? From the use of the term "hydrophobic silane" in claim 6, it appears that the term "hydrophobic organic group" includes the definitions of the variables as recited in claim 6. Is the term "hydrophobic organic group" of claim 5 limited to the definitions the variables as defined in claim 6 or does it include other moieties?

e) In claim 6, it is unclear what is meant to be included by the term "substituted".

f) Claim 15 does not make sense. It is unclear what is meant by the term "immunoactive substrate". It is unclear how the terms "immunoactive substrate", "solid phase", "carrier for immunoassay" and "resulting carrier" differ from or are related to one another. It is unclear what the term "surface thereof" relates to. It is unclear what is meant by the term "exposed area of said hydrophobic material". Is all of the hydrophobic material "coated" with the "amphiphatic substance"? It is unclear what is meant by the term "hydrophobic material"; this term is not limited to the compounds of the structures of claim 1. The use of the term "obtainable by" does not require that the product be produced by the stated method; therefore, the claim is indefinite as to its exact scope (suggestion: use the term "obtained by").

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7) Claims 1-3, 5-7, 9-13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of dimethylpolysiloxane (specification, page 10, line 9) and octadecyltriethoxysilane (specification, page 14, lines 1-2), does not reasonably provide enablement for the use of any other compound encompassed by formulas [I] and [II] of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

8) Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the coating of a compound of formula [I] or [II] of claim 1 on a "carrier", does not reasonably provide enablement for any other type of attachment to the "surface", e.g. covalent bonding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

9) Claims 1-3, 5-7, 9-13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to describe methods for the preparation of all of the compounds of formulas [I] and [II] of claim 1. The compounds dimethylpolysiloxane (specification, page 10, line 9) and octadecyltriethoxysilane (specification, page 14, lines 1-2) are commercially available. However, the specification fails to describe methods which would produce the remaining compounds encompassed by formulas [I] and [II] of claim 1 and there is no indication in the specification that the remaining compounds are commercially available. It is further noted that the "circular" compounds of formula [II] are not analogous to the "linear" compounds of formula [I] and the methods of preparation of the formula [II] compounds would be expected to be different from the methods of preparation of the formula [I] compounds.

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10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11) Claim 1 is drawn to a “carrier” with a compound of the formula [I] and/or [II] on “at least” the surface thereof. The “for use in” limitation (“for immunoassay”) is not a limitation on the product per se. It is noted that the prior art is replete with numerous descriptions of compositions which meet the requirements and therefore anticipate the compositions of claim 1. The claim 1 composition containing the compound of formula [I] wherein “a” is “0” is readable on a carrier with trimethoxysilane (TMS) on the surface. The open-ended “comprises” claim terminology is inclusive of additional moieties in the composition. Applicants are advised that only a sample of all applicable references have been used in the rejections under 35 USC 102 below. In order to expedite prosecution, applicants should limit the claims to what they consider the *actual invention* to be.

10) Claims 1-6 and 9-13 are rejected under 35 U.S.C. 102(b)/(e) as being anticipated by each of Delamarche et al {Science, vol. 276,(5313) 779-781 (1997)}, Charmot et al {US 5,178,947}, Bogart et al {US 5,468,606}, Kossovsky {US 5,798,220}, Becker et al {US 5,187,066}, Dubrow et al {US 5,037,667}, Kiaei et al {US 5,639,626} or Anstett et al {US 6,140,263}, CIBA {EP 713,095} or Chu {US 6,284,194}.

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Claim 1 is drawn to a "carrier" with a compound of the formula [I] and/or [II] on the surface thereof. The "for use in" limitation ("for immunoassay") is not a limitation on the *product per se* and there is no limitation on how the "silicon compound" is applied to the surface (e.g. covalent bond or coating). The open-ended "comprises" terminology of the claims does not exclude the presence of other components/moieties in the composition. The prior art references describe and therefore anticipate the claimed two-component compositions. See:

Delamarche et al: page 2 of 9: poly(dimethylsiloxane) applied to Au, glass and silicone dioxide surfaces ;

Charmot et al: col. 4, lines 8-11 ; col. 1, line 67 – col. 2, line 40;

Bogart et al: col. 52, lines 1-16;

Kossovsky: col. 3, line 61 "dimethylpolysiloxane" (Note that claim 1 includes the case where the "carrier" is the compound of formula [I] or formula [II] *per se*, i.e. the "carrier" comprises the compound functioning as both the "carrier" and the agent on the "surface" of the "carrier".);

Becker et al: abstract and col. 6, line 64 – col. 7, line 13;

Dubrow et al: abstract;

Kiae et al: abstract and col. 4, lines 1-53;

Anstett et al: col. 4, lines 4-7;

CIBA: page 3, line 43 – page 4, line 45;

Chu: abstract and col. 8, lines 19-20 (SILWET).

11) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 10, 2005

Mary E. Ceperley
Mary (Molly) E. Ceperley
Primary Examiner
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